

Navajo Nation Human Research Review Board Meeting Agenda

DATE: October 17, 2017

TIME: 9:00 AM

PLACE: NDOH West Conference Room,
Window Rock, AZ

MEMBERS:

Dr. Mark C. Bauer, Ph.D. - Scientific Education
Beverly Becenti-Pigman, Chair – Community
Dr. David Begay, Ph.D. - Scientific Education
Rebecca Izzo-Manymules, MPH, Ph.D. (C) – Education
Ursula Knoki-Wilson, MSN, MPH - Nursing
Wallace McGilbert - Community
Dr. Raymond Reid, MD - Medicine
Dr. Kalvin White, Ph.D. - Scientific Education

OLD BUSINESS:

- I. Meeting Call to Order:
- II. Roll Call:
 - Invocation
 - Introductions:
- III. Review and Approval of Agenda:
- IV. Review and Approval of June 20, July 18, August 16, 2017 Meeting Minutes:

NEW BUSINESS:

- V. Quarterly Reports:
- VI. Serious Adverse Events (SAEs):
- VII. New Presentations:
- VIII. Returning Presentations:
- IX. Noon Hour Discussion:
- X. Manuscripts / Abstracts to submit NNHRRB applications
- XI. Announcements and Adjournment:

Navajo Nation Human Research Review Board
IRB 10-17-2017 Meeting Agenda

VII. NEW PRESENTATION(S)

1. NNR-17.287T PI: Sehn, Hannah

Understanding the Structural Barriers and Opportunities to Improve Cancer Treatment on Navajo Nation,
Reason on New Title

Description: Request Review and Approval of New Study

2. NNR-17.288T PI: Dabelea, Dana M.D.

Tribal Turning Point (TTP)

Reason on New Title

Description: Request Review and Approval of New Study

3. NNR-17.289T PI: Nawrocki, Rachel B.S.

Youth Builders

Reason on New Title

Description: Request Review and Approval of New Study

4. NNR-17.290T PI: Tayah, Roberta

Family Stories: How Homes and Schools Influence and Navigate Career Pathways form Navajo High School Students

Reason on New Title

Description: Request Review and Approval of New Study

VIII. RETURNING PRESENTATION(S)

1. NNR-02.106 PI: Dabelea, Dana M.D.

SEARCH for Diabetes in Youth Study

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July - September 2017 period

2. NNR-06.188 PI: Gittelsohn, Joel Ph.D.

Expanding and Sustaining a Successful Food-Store Based Program to Improve Diet and Risk for Obesity and Other Chronic Disease in American Indians

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July - September 2017 period

3. NNR-15.208 PI: Pollari, Lynette

Dine Cultural Sustainability through Settlement Form: "Finding Patterns for New Navajo Neighborhoods:

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering August 19 - November 19, 2017 period

4. NNR-16.234 PI: Chief, Karletta Ph.D.
To Litso, the water is Yellow: Investigating short term exposure and risk perception of Navajo communities to the Gold King Mine toxic spill
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering 1) January – March, 2) July - September 2017 period. Attachment Summer/Fall News Letter.
5. NNR-17.266T PI: Ingram, Jani C Ph.D.
Mutton Consumption Survey
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May 22 - August 21, 2017 period
6. NNR-17.267 PI: Rock, Tommy MA, BA
Radioactive Nation: Navajo's History with Uranium
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May 25 - September 21, 2017 period
7. NNR-16.249 PI: Melton, Ada Pecos MPA
The National Baseline Study (NBS) Examining Violence against American Indian and Alaska Native Women Living in Indian Country and Alaska Native Villages.
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May 17 - November 7, 2017 period
8. NNR-02.110 PI: Knowler, William MD
Diabetes Prevention Program Outcomes Study (DPPOS)
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering August 20, 2016 - August 20, 2017 period.
9. NNR-02.111 PI: Reid, Raymond M.D.
Effects of Maternal Influenza Vaccination on Respiratory Disease among Infants
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering August 20, 2016 - August 20, 2017 period
10. NNR-09.253 PI: Reid, Raymond M.D.
Impact of 13-valent pneumococcal conjugate vaccine (PVC13) on pneumococcal disease and colonization among Native American communities
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering August 18, 2016 - August 18, 2017 period
11. NNR-09.255 PI: Reid, Raymond M.D.
Pilot Study of the Association between Acute Gastroenteritis and Water Quality, Availability, and Handling Practices on the Navajo Nation
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering August 18, 2016- August 18, 2017 period

12. NNR-15.229 PI: Carre, Nancy C.
The Effect of Educational Narratives on High School Persistence among Navajo Girls
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering February 16, 2016 - February 16, 2017 period
13. NNR-16.247 PI: Bender, Bruce G. Ph.D.
Creating an asthma collaboration to reduce childhood asthma disparities on the Navajo Nation
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering September 20, 2016 - September 20, 2017 period
14. NNR-16.260 PI: Eddie, Regina S. MS, RN
A Socio-Ecological Analysis of Childhood Obesity and School Nutrition Policies and Practices in Select Elementary and Middle Schools on the Navajo Reservation.
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering October 18, 2016 - October 18, 2017 period
15. NNR-05.174 PI: Reid, Raymond M.D.
In-home Prevention of Substance Abuse Risk in Navajo Teen Families
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request for Study covering October 17, 2017 - October 17, 2018 period
16. NNR-11.346 PI: Reid, Raymond M.D.
Together on Diabetes Study: Evaluation of a pilot Diabetes Prevention and Management Program for American Indian Youth.
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering December 21, 2017 - December 21, 2018 period
17. NNR-15.223 PI: Richards, Jennifer MPH
Formative Research to Inform the Development of an Intergenerational Strengths-Based Program for American Indian Girls as they Transition to Adulthood.
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering December 15, 2017 - December 15, 2018 period
18. NNR-15.232 PI: Hammitt, Laura M.D.
Etiology of pneumonia and burden of pneumococcal pneumonia in hospitalized American Indian adults
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request of Study covering November 17, 2018 - November 17, 2018
19. NNR-09.262 PI: Shirley, Valerie J. Ph.D.
The Cultural Hybridization of Dine Students and Teachers Inside the Classroom: Examining Interactions with a Culturally Dine Based Curriculum in a Westernized School Student
Reason on Close Study
Description: Request Acceptance and Approval to Request Close-out of Study

20. NNR-06.182 PI: Wallerstein, Nina Dr.PH

Listening to Each Other Curriculum Development Research Project

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April 22 - August 21, 2017 period.

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 21, 2016 - October 21, 2017 period.

Reason on Continuation Request

Description: Request Acceptance and Approval of Request for Continuation covering October 21, 2017 - October 21, 2018 period.
Attachment of UNM IRB Continuation of Study Approval Letter

21. NNR-07.198 PI: McGrath, Jane W. MD

Envision New Mexico Pediatric Overweight Learning Collaborative

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering March 17 - June 16, 2017 period

Reason on Change in Investigators

Description: Request Acceptance and Approval of Change of Investigator Dr. Kirsten Bennett, PhD, RD, LD. Attachments: Part 5 Certification, IRB Approval Letter, CV.

22. NNR-07.212 PI: Sanderson, Priscilla Ph.D.

A Pilot Investigation of Colorectal Cancer Screening for Awareness, Practices, and Recommendations on the Navajo Reservation

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 1 - August 31, 2017 period

Reason on Annual Report

Description: Request Acceptance and Approval of Continuation Request covering September 16 - August 31, 2017 period

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering September 1, 2017 - August 31, 2018 period

23. NNR-11.323 PI: Lewis, Johnnye L. Ph.D.

Navajo Birth Cohort Study (NBCS)

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 23 - August 22, 2017 period

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 23, 2016 - August 22, 2017 period

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 23, 2017 - August 23, 2018 period. Attached UNM Continuation Approval Letter

24. NNR-11.325 PI: Hammitt, Laura MD

Study of a vaccine for reducing ear and lung infections in children

Reason on Abstract Submission

Description: Request Review and Approval of Three Abstracts for Conference Presentation for World Society for Pediatrics Infectious disease (WSPID) 2071 in Shenzhen, China on December 2-5, 2017 (approved at July 18 meeting)

25. NNR-13.113 PI: English, Kevin C. Dr.PH

Tribal FOBT Study

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 21 - August 20, 2017 period

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 21, 2016 - August 20, 2017 period.

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 21, 2017 - August 21, 2018 period

26. NNR-13.158 PI: Dabelea, Dana M.D.

Tribal Turning Point Program (TPPP) (A Feasibility Pilot Study)

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 1 - August 16, 2017 period

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 16, 2016 - August 16, 2017 period

Reason on (Other)

Description: Request Acceptance and Approval to Close-out Study.

Reason on Final Report

Description: Request Acceptance and Approval of Final Report covering August 20, 2013 - August 16, 2017 period.

27. NNR-14.171 PI: Henderson, Davis E Ph.D.

CELF - 4 and PPVT - 4 among Navajo Students

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June - August 2017 period

Reason on Revised Protocol

Description: Request Review and Approval to Transfer Protocol from ASU to University of Mississippi

Reason on Data Assessment

Description: Request Review and Acceptance of Data Analysis and Publication.

28. NNR-15.215 PI: Henderson, Davis E Ph.D.

Dynamic Assessment of Narratives among Navajo Preschooler

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 18, 2016 - October 18, 2017 period

Reason on Abstract Submission

Description: Request Review and Approval of Data Analysis and Publication: CELF - Preschool 2nd Edition.

Reason on Revised Protocol

Description: Request Review and Approval to Transfer Protocol from University of Arizona to University of Mississippi

29. NNR-15.222 PI: Huyser, Kimberly R. Ph.D.

The American Indian Reservation as a source of Risk and Resilience against Psychological Distress: An Analysis of Two American Indian Tribes

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) October 1 - December 31, 2016; 2) January 1 - March 31, 2017; 3) April 1 - June 30, 2017; 4) July 1 - October 19, 2017 periods.

- Reason on** Annual Report
Description: Request Acceptance and Approval of Annual Report covering October 19, 2016 - October 19, 2017 period
30. NNR-15.224 PI: Watanabe, Kohei
- Ethnography of Laughter: Laughter of Dine and Creation of Hozo**
- Reason on** Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 20 - July 19, 2017 period
- Reason on** Annual Report
Description: Request Acceptance and Approval of Annual Report covering October 20, 2016 - October 20, 2017 period
- Reason on** Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering October 20, 2017 - October 20, 2018 period
31. NNR-16.254 PI: Reid, Raymond M.D.
- Evaluation of Native Vision Year Round Program**
- Reason on** Amendment
Description: Request Acceptance and Approval of Amendments to Protocol: 1) Additional time point for the youth survey, 2) New survey for Elementary age youth. Revised Forms: A) Parent Permission Form for parent of youth under 18 years old; B) Assent Form for youth under 18 years old; C) Consent Form for participants who are 18 years of age or older, D) Survey for elementary age youth participants
32. NNR-17.277 PI: Moore, Kelly R MD.
- Stopping Gestational Diabetes in Daughters and Mothers - Phase 2**
- Reason on** Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 18 - October 18, 2017 period
- Reason on** Addendum
Description: Request Acceptance and Approval of Addendum to Protocols as Directives for Approval (7-18-17):1) Dr. Charron-Prochownik Certification, 2) Northern Navajo Agency Council Supporting Resolution, 3) Revised Consent Form, 4) finalized survey Questionnaires.
33. NNR-17.281 PI: Garrison, Nanibaa' Ph.D.
- Perspectives on Genetic Research in the Navajo Nation**
- Reason on** Addendum
Description: Request Acceptance and Approve of Addendums to Protocol: 1) Revised Signed Consent Form; 2) Focus Group Study Consent Form; 3) Navajo Nation Historic Preservation Department Permit; 4) Recruitment Flyer; 5) Interview Question Guide; 6) In-depth Interview Questions; 7) University of Washington IRB Approval Letter.
34. NNR-17.282 PI: Hammitt, Laura M.D.
- A Study to Evaluate the Efficacy of Maternal Immunization with RSV F vaccine in Preventing RSV Lower Respiratory Tract Infection in Young Infants (RSV-M-302)**
- Reason on** Amendment
Description: Request Acceptance and Approval of Amendments to be added to Protocol; 1) Consenting Flip Chart; 2) Phone Script for Surveillance; 3) Texting Script for Surveillance; 4) SAE Reporting Form; 5) Memory Aide; 6) Study Visit Info graphing; 7) Chart Flag

35. NNR-16.237 PI: Tapaha, Oliver, Ph.D.
Dine' (Navajo) Elementary Teachers' Perspectives on Dine'k'ehgo Nanitiin Idine' Based Instruction): An Ethnographic Study
Reason on: Dissertation
Description: Request Review and Acceptance of Copy of Dissertation Titled: "We Live it" Stories of Cultural Resilience, Dine'ehgo Nanitiin (Dine-Based Instructions) and Navigating between University and Tribal Institutional Review Boards, attachment (signed consent forms)
36. NNR-16.245 PI: Gittelsohn, Joel PhD, MS
Engaging Tribal Policy Makers to Sustain Improvements to the Food and Physical Activity in American Indian Communities (OPREVENT2)
Reason on: Addendum
Description: Request Acceptance and Approval of Addendum of : 1) Information Posters, 2) Booklets
37. NNR-17.282T PI: Gittelsohn, Joel PhD, MS
Multilevel Obesity Prevention Trial for American Indian Community (OPREVENT)
Reason on: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July – September 2017 period.

IX. Noon Hour Discussion:

- X. Abstracts to submit NNHRRB applications 1) Culturally Responsive Project Based Learning STEM Curriculum for Native American Classroom - 2) Having Opportunities Promotes Excellence: Developing Scholar Identities Among Underserved Youth with High Potential IHOPE+SIM) – *Dr. Marcia Gentry, Ph.D.*

XI. Announcements and Adjournment:

Last page and end of Agenda